

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Steris Corporation
5 Sunnen Drive
St. Louis
Missouri
63143
USA

Facility ID Number: F007659

Holds Certificate No:

MDSAP 812095

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and development, manufacture and distribution of sterile and non-sterile surgical instruments, electrosurgical RF instruments and sterilization containers and accessories for the areas of Cardiovascular, Vascular, Thoracic, Ear, Nose and throat, General Hospital, Laparoscopic, Neurosurgical, Obstetrical, Gynecological, Urological, Ophthalmic, Orthopedic, Plastic surgery, and Microsurgical and Dental.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-11-20

Effective Date: 2024-11-20

Expiry Date: 2027-11-19



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 812095**

Location	Registered Activities
Steris Corporation 5 Sunnen Drive St. Louis Missouri 63143 USA Facility ID Number: F007659	The design and development, manufacture and distribution of sterile and non-sterile surgical Instruments and electrosurgical RF instruments for the areas of Cardiovascular, Vascular, Thoracic, Ear, Nose and throat, Laparoscopic, Neurosurgical, Obstetrical, Gynecological, Urological, Ophthalmic, Orthopedic, Plastic surgery, and Microsurgical and Dental. The design and development of sterilisation containers.
Steris Corporation 17820 Englewood Drive Cleveland Ohio 44130 USA Facility ID Number: F007670	The manufacture, and distribution of sterilisation containers and accessories.
Steris Corporation Kantstrabe 33/1 Wurmlingen 78573 Germany Facility ID Number: F007671	The manufacture of non-sterile surgical Instruments and electrosurgical RF instruments for the areas of Cardiovascular, Vascular, Thoracic, Ear, Nose and throat, Laparoscopic, Neurosurgical, Obstetrical, Gynecological, Urological, Ophthalmic, Orthopedic, Plastic surgery, Microsurgical and Dental.

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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